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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,121	02/16/2001	Robert C. McIver	81455-464	2558

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,121	MCIVER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 02 September 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Applicant's Arguments/Remarks filed 09/02/04 is acknowledged.

Claims 1-17 are pending. No amendments to the claims have been made. Claims 1-17 are rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 8, 10, 11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto (EP 0 389 700 A1).

Goto teaches a soft capsule and globular material prepared from (natural high- molecular) agar-agar as the base material that is applied to pharmaceuticals, chemicals, cosmetics, foodstuffs, miscellaneous goods and the like, wherein the soft capsule comprises sorbitol (carbohydrate), plasticizers, stabilizers, colorant, perfume, disintegrator assistant and corrigent (see reference page 3, lines 18-24 and Abstract).

The examples demonstrate various agar-agar containing capsule formulations.

Example 1, pgs. 3-4, Goto teaches a vegetable soft capsule containing medicine Vitamin E, soybean oil and agar-agar (25 mg) and glycerin and water as the capsule film.

In Example 6, pg. 6, a soft capsule for water-containing foodstuff is taught whereby the soft capsules each containing perfumes, seasonings and nutritive substances were prepared and the resultant capsules were admixed with custard pudding, yogurt, milk or the like.

Similarly, in Example 8 on pg. 6, Goto teaches a well-nourished soft capsule for medicated drink (medicine).

Regarding the claimed percentages or amounts, no criticality is seen in the claimed percentages/amounts, since it would have been obvious to one skilled in the art that suitable percentages or amounts can be determined through the use of routine or manipulative experimentation.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto (EP 0 389 700 A1).

Goto teaches a soft capsule and globular material prepared from (natural high- molecular) agar-agar as the base material that is applied to pharmaceuticals, chemicals, cosmetics, foodstuffs, miscellaneous goods and the like, wherein the soft capsule comprises sorbitol (carbohydrate), plasticizers, stabilizers, colorant, perfume, disintegrator assistant and corrigent (see reference page 3, lines 18-24 and Abstract).

In Example 5, pg. 5, Goto teaches a soft capsule for water-containing cosmetics wherein the soft capsule contains perfume, oil, nutritive substance, agar-agar, glycerin. The soft capsule was then mixed with water-containing cosmetics such as lotion, cream, milky lotion, *shampoo and the like.* Globular materials can be prepared with these ingredients and may then be mixed with massage cream to serve a scrub cosmetic.

Example 10 demonstrates a soft capsule for bath lotion, comprising agar-agar and perfumes.

Claims 1-11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes *et al.* (WO 85/03414).

Barnes *et al.* teach an extrudable encapsulation particulate matrix composition having improved loading capacity for oils, flavors, fragrances, agricultural chemicals, drugs, etc., whereby the matrix composition contains carbohydrates such as maltodextrin (starch hydrolysate), modified starches and agar-agar in an amount of 0.25-5% (instant claims require 1-7%). The maltodextrins have a dextrose equivalent being in the range of 3-40. (see reference pages 2-9).

According to Barnes *et al.*, the encapsulating matrix composition has an improved loading capacity of up to about 40%. A particulate composition comprising the foregoing matrix composition in combination with liquid or volatile active ingredients is also taught, whereby other ingredients include water, emulsifiers, and viscosity agents in effective quantities (generally below 10%) (pg. 5, lines 2-19).

The role of the maltodextrin is to provide matrix bulk, and an emulsion, prior to extrusion, of reasonable viscosity. Various modified starches can be used, such as 'Amaizo ARD 2326', which is an octenyl succinic anhydride derivative. Either of these components may be replaced in part with natural gums, i.e., gum acacia, gum arabic, corn syrup solids having a dextrose equivalent below about 40, or sucrose. Sucrose can also be replaced with equivalent

amounts of glucose, sweeteners, cellulose compounds or polyhydric alcohols such as sorbitol, mannitol or the like (pg. 5, line 23 – pg. 6, line 16).

Flavor systems containing high levels of water (fruit essences) can be encapsulated according to the teachings of Barnes *et al.* The composition may contain about 20% maltodextrin, about 30% Capsul, and about 40% flavor, of which 20% is oil and 80% is carrier. Various flavoring agents may be employed, for example orange oil, lemon oil, grapefruit oil, fruit essence extracts, etc. Mixtures of flavoring agents may also be used. It is preferred to add an edible oil and/or an edible emulsifying agent to the purified fruit essence so that it will emulsify properly with the matrix (pg. 7-pg. 8, line 19). The proportion of the flavoring agent to be incorporated in the carrier base may be varied depending on the flavor strength desired in the final product. Active agents include organoleptics i.e., flavors or fragrances, agricultural chemicals, flavor enhancers, pharmaceuticals, etc. These encapsulating matrices materials are soluble in water to release the active ingredient. They may be used as ingredients of candy or lozenges or breath deodorants (pg. 8, line 27- pg. 9, line 4).

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sair *et al.* (US Pat. No. 4,232,047).

Sair et al. teach a food supplement concentrate of an ingestible agent such as a seasoning, flavoring, essential oil, vitamin, mineral and mixtures thereof encapsulated, enveloped or encased as a dispersed microphase within a matrix of an encapsulating medium such as a starch, protein, flour, modified starch, gum and mixtures thereof. The concentrate is prepared by mixing the edible agent and the encapsulating medium with a limited quantity of water adequate to

permit conversion of the mixture, under applied *extrusion* pressure and controlled heat, to provide a dense glassy extrudate with ingestible agent dispersed therethrough in microform (see Abstract).

The method of Sair et al. has been found particularly useful in the encasement of essential oils or artificial flavors, whereby the extruded product can be ground or otherwise reduced to any desired particle size (column 4, lines 31-33; col. 5, lines 18-27). The examples demonstrate stabilized extruded products whereby extrusion, drying and grinding were conducted.

Response to Arguments

Applicant's arguments filed 09/02/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the rejection of claims 15 and 17 under 35 U.S.C. §103(a) over Goto et al. (EP 0,389,700) stating, "The use of such a small and specific amount of agar agar is critical, since it results in the formation of a gel layer in water and stability in aqueous environments for a prolonged period of time. The use of prehydrated agar agar is not taught. The rehydration process of the carrier, including agar agar, results in the prevention of loss of flavor or fragrance ingredients to the surrounding water. The present invention achieves advantages, such as gel barrier formation in aqueous environment, prolonged stability in water and controlled release of active ingredients."

These arguments have been fully considered, but were not found to be persuasive. Goto et al. teach a soft capsule prepared from agar-agar as the base material, which is applied in various applications, including pharmaceuticals, chemicals, cosmetics, foodstuffs, miscellaneous

goods and the like. Goto et al. teach that the agar agar has distinct characteristics than previously employed soft capsules of the art. Goto et al. teach that the agar agar satisfies substantially all of the necessary conditions as a film base material, which include conditions of stability with age, film strength, heat bond performance and safety (see page 2, lines 47-53 & page 3, lines 34-45). Example 5 on page 5, further demonstrates a soft capsule for water-containing cosmetics, wherein the film did not dissolve in water for a long period of time. Moreover, in comparison with the agar agar globular materials, gelatin globular materials dissolved with age so they were lacking in stability.

Secondly, Applicant argued regarding the rejection of claims 1-11 and 15-16 under 35 U.S.C. §103(a) over Barnes et al. (WO 85/03414) stating, "Agar agar is not a required element of the carrier matrix but only an optional emulsifier. Barnes does not disclose a single example of a composition containing agar agar. For the same reasons, Barnes fails to recognize and utilize advantages of agar agar when used in capsules and put into water. Barnes does not specify how agar agar should be employed in its encapsulating composition. Barnes lists agar agar merely as a possibly useful material."

Applicant's arguments were carefully considered, but were not found persuasive. Barnes teaches desirable ingredients, such as emulsifiers, of which agar agar is also included, in an amount fromn 0.25 to 5% (instant claims recite 1-7%). The issue of agar agar being an 'optional' component is a limitation that cannot be ignored in the art. Barnes further teaches the incorporation of emulsifiers contained in effective quantities (generally below 10%) on page 5, lines 14-19. Applicant's argument that 'agar agar is not exemplified' is not persuasive since the instant claims are not limited to the examples taught by the prior art. Barnes teaches the

desirability of employing emulsifiers, and teaches agar agar to be among the desired selection of emulsifiers. Applicant's argument that 'Barnes fails to recognize and utilize advantages of agar agar' is not persuasive since the mere teaching or suggestion of the ingredient agar agar in matrix compositions is sufficient and therefore the advantages imparted by those ingredients, particularly agar agar, would be inherently incorporated into the formulation itself. Since Barnes teaches the desirable use of agar agar among the emulsifiers, the benefits and advantages provided from the agar agar would also be present. The prior art teaches a similar formulation, utilizing similar components, used in the same field of endeavor as that desired by Applicants.

Lastly, Applicant argued regarding the rejection of claims 12-14 under 35 U.S.C. §103(a) over Sair et al. (US '047) stating, "Sair is completely silent on the use of agar agar, let alone the specific quantities of agar agar. Sair teaches away from the present invention and leads one skilled in the art away from looking at particular matrix components."

These arguments have been thoroughly considered, but were not found persuasive. Sair *et al.* was relied upon for the teaching that it is well known to incorporate process steps, such as melt extrusion, grinding and the like, in food supplement formulations comprising flavorings, starches, oils, nutrients, gums, etc. The methods employed by Sair *et al.* result in the useful encasement of essential oils and flavors. Sair *et al.* further teach that the dispersible agents are retained as being stable and protected (col. 6, lines 29-30).

Regarding the instantly claimed amounts of agar agar, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One skilled in the art through routine or manipulative experimentation could readily determine suitable ranges, to obtain optimal results, as these are indeed variable parameters within the art.

The prior art of record clearly addresses the issue of stability, film strength, heat resistance and safety. The prior art teaches similar components for use in the same field of endeavor as that desired by Applicants. Thus, the instant invention, when considered as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

December 21, 2004

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